

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

**IN RE: JOHNSON & JOHNSON TALCUM
POWDER PRODUCTS MARKETING,
SALES PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

**MDL No. 16-2738 (FLW-
LHG)**

***THIS DOCUMENT RELATES TO ALL
CASES***

**PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF LAW IN
SUPPORT OF ITS MOTION TO EXCLUDE THE EXPERT OPINIONS OF
DEFENDANTS' MOLECULAR BIOLOGISTS
DRS. NEEL, SHIH, BOYD, AND BIRRER**

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The Plaintiffs' Steering Committee ("PSC") respectfully submits this motion, pursuant to Fed. R. Evid. 104 (a), 702, 703 and 403, to exclude the testimony of Defendants' molecular biologists, Drs. Neel, Shih, Boyd, and Birrer.¹

I. INTRODUCTION

The Johnson & Johnson Defendants (hereinafter, "Defendants") have identified four putative expert witnesses – Drs. Neel, Shih, Boyd, and Birrer – to offer various opinions, including that there is no plausible molecular mechanism by which the Talcum Powder Products at issue² in this case can cause ovarian cancer.

Under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 526 U.S. 579 (1993), Defendants bear the burden, as the party offering these experts, to demonstrate that these experts are qualified to offer the opinions they render on a given subject and that they have used a reliable scientific method to reach their opinions. *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 418 (3d Cir. 1999). Defendants have failed to meet their burden because the opinions of Drs. Neel, Shih, Boyd, and Birrer are methodologically unreliable. In addition, they go far beyond their areas of expertise. Therefore, the PSC respectfully requests that the Court preclude these witnesses from testifying to the expert opinions they seek to offer.

¹ Benjamin G. Neel, MD, PhD ("Dr. Neel"); Ie-Ming Shih, MD, PhD ("Dr. Shih"); Jeffrey A. Boyd, PhD ("Dr. Boyd"); and Michael Birrer, MD, PhD ("Dr. Birrer").

² *I.e.*, Johnson & Johnson's Baby Powder and Shower-to Shower products.

These expert witnesses claim experience in what may broadly be described as the molecular biology and/or molecular genetics of cancer,³ and with the exception of Dr. Birrer, none have prior experience in assessing the causality of putative carcinogens.

For example, Dr. Neel asserts in his Expert Report that his “major expertise is in the area of *cancer cell signaling*, most notably involving protein-tyrosine phosphatases (PTP’s).”⁴ Dr. Shih’s research focuses on endometriosis and “the *molecular landscapes* in different types of ovarian cancer and identifying *novel genes and pathways* involved in cancer initiation, chromatin remodeling,

³ See, e.g., March 19, 2019, Deposition of Dr. Neel (“Neel Dep.”) attached as **Exhibit A**, at 14:4-5 (“cancer biology and cellular molecular biology field”), 27:14-20 and 28:23 – 29:1 (work on identifying SHIP-1 and -2 inhibitor proteins); March 26, 2019, Deposition of Dr. Shih (“Shih Dep.”), attached as **Exhibit B**, at 67:22-68:1 (“My job here is served as an expert in cancer biology and gynecology pathology to answer whether talc is – is causal or not”); April 8, 2019, Deposition of Dr. Boyd (“Boyd Dep.”), attached as **Exhibit C**, at 60:2-3 (“cancer geneticist and a molecular diagnostician”); and the March 29, 2019, Deposition of Dr. Birrer (“Birrer Dep.”), attached as **Exhibit D**, at 15:8-9 (“the genomics, the molecular basis for ovarian cancer.”).

⁴ See February 25, 2019, Expert Report of Dr. Neel (“Neel Report”), attached as **Exhibit E**, at 2 (emphasis added). Dr. Neel is currently a tenured Professor of Medicine and the Director of the Laura and Isaac Perlmutter Cancer Center at New York University. He received a Ph.D. in Viral Oncology at Rockefeller University in 1982 and an M.D. from Cornell University Medical School the following year. Since then, he has held positions at a variety of respected medical/research institutions, including Beth Israel Hospital, Harvard Medical School, and the University of Toronto/Princess Margaret Cancer Center, before transitioning to NYU in 2015.

chromosomal instability, cytokinesis and tumor invasion in ovarian cancer.”⁵ Dr. Boyd’s research similarly “focuses on the *genetics and molecular genetics* of gynecologic and breast cancers.”⁶ Likewise, Dr. Birrer’s “research efforts have *focused almost entirely on the molecular genetics* of ovarian cancer,” including “characterize[ing] the molecular events in the development of ovarian cancer.”⁷

⁵ See February 25, 2019, Expert Report of Dr. Shih (“Shih Expert Report”), attached as **Exhibit F**, at 2 (emphasis added). Dr. Shih graduated from Taipei Medical University in 1988 and received a Ph.D. from the University of Pennsylvania in 1993. He then transitioned to Johns Hopkins University, where he is currently the Richard TeLinde Distinguished Professor of Gynecologic Oncology at the Johns Hopkins Medical Institutions.

⁶ February 25, 2019, Expert Report of Dr. Boyd (“Boyd Report”), attached as **Exhibit G**, at 2 (emphasis added). He is Chair and a tenured Professor in the Department of Human and Molecular Genetics the Herbert Wertheim College of Medicine at Florida International University (“FIU”). He is also a professor of Obstetrics and Gynecology and Associate Dean for Basic Research and Graduate Programs there. Dr. Boyd received his undergraduate degree at Duke University and his Master and Ph.D. degrees at North Carolina State University and worked at several respected institutions before transitioning to FIU in 2015.

⁷ February 25, 2019, Expert Report of Dr. Birrer (“Birrer Report”), attached as **Exhibit H**, at 2 (emphasis added). Dr. Birrer is the Director of the University of Alabama at Birmingham Comprehensive Cancer Center (“UAB”). He received his undergraduate degree from Rensselaer Polytechnic University and his M.D. and Ph.D. from the Albert Einstein College of Medicine, where his principal focus was microbiology and immunology. Dr. Birrer then worked at several respected institutions, including work on the molecular genetics of lung cancer at the National Cancer Institute, before transitioning to UAB in 2017.

II. SUMMARY OF ARGUMENT

The common opinion that Drs. Shih, Neel, Boyd, and Birrer each offer is that there is no plausible molecular mechanism by which it makes biological sense⁸ that the Johnson & Johnson Talcum Powder Products at issue in this case can cause ovarian cancer. Yet, when asked whether known or possible carcinogens are constituents of the Talcum Powder Products— incredibly, they each admit that they have absolutely no idea.

In other words, they don't know what's in it – but whatever it is – they somehow know it's not biologically plausible that the association seen in the observational data between talcum powder and ovarian cancer “makes sense.” It does not take more than common-sense to conclude that these experts' opinions are based on sheer speculation and amount to nothing more than *ipse dixit*. It is wholly unreasonable –and unreliable— for a molecular biologist or molecular geneticist to offer an opinion on the plausibility (or lack thereof) of the mechanism by which an alleged carcinogen may act, when the scientist does not even know the constituents of products that are alleged to be carcinogenic. The presence of known or possible

⁸ As discussed in more detail *infra*, Defendants' proffered witnesses apply the wrong standard. The correct standard for biological plausibility is discussed in detail in *PSC's Mem. Support of Mot. To Exclude the Opinions of Defendants Epidemiology Experts Drs. Ballman, Merlo, Diette and Borak*, filed concurrently herewith, at 66-69, esp., e.g., fn. 123-125 & 127. In an effort to conserve scarce judicial resources, this discussion is incorporated by reference as if set forth entirely herein.

carcinogens in Johnson & Johnson's Talcum Powder Products provides biologic evidence supporting the causality of the consistent association detected in the observational studies.⁹

These witnesses have unanimously conceded they have no opinion on, or knowledge of, the components of the Talcum Powder Products at issue in this case. This is fatal to their opinions on biological plausibility. Biologic plausibility addresses the basic question of "does that association make biological sense?" How can a scientist express a reliable opinion about the biological plausibility of whether a product causes an endpoint (ovarian cancer) when the scientist does not even know the constituents of the product at issue? Moreover, in this case, there is credible evidence that the Talcum Powder Products contain multiple known carcinogens, including asbestos, fibrous talc, nickel and chromium, each of which can and do

⁹ As the Court is well aware, the PSC alleges that there are multiple *known carcinogens* in Johnson & Johnson's Talcum Powder Products: asbestos, fibrous talc (talc in an asbestosiform habit), nickel and chromium. See International Agency for Research on Cancer. (2012). Arsenic, Metals, Fibres and Dusts, Vol 100C, A review of human carcinogens. In IARC, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*. Lyon, France: World Health Organization, attached hereto as **Exhibit I**.

In addition, there are numerous *possible carcinogens* in the Talcum Powder Products, including platy talc, cobalt, and multiple fragrance chemicals. See IARC (2010) *Monographs on the Evaluation of Carcinogenic Risks to Humans: Volume 93 - Carbon Black, Titanium Dioxide, and Talc*. Lyon, France: International Agency for Research on Cancer, attached hereto as **Exhibit J**; see also IARC (2012); November 16, 2018 Expert Report of Michael M. Crowley, PhD.

provide biologic evidence consistent with the inference that Talcum Powder Products can cause ovarian cancer, *i.e.*, a causal explanation for the association seen between these products and ovarian cancer “makes sense.”¹⁰ So, these experts are expressing an opinion without possessing (or ignoring) the necessary information that is critical to a proper foundation for their opinions.

These experts are molecular scientists. As such, they should be expressing opinions based on a molecular study of whether specific constituents can cause an endpoint. They have not done that. Instead they have attempted to bootstrap their opinion to epidemiological studies even though they admit they are not epidemiologists.

The opinions of these four experts have been constructed in a manner to attempt to avoid the reality of the causal connection between the use of Talcum Powder Products and ovarian cancer. The construct is built around the proverb - “*Hear No Evil, See No Evil, Speak No Evil.*” None of them have knowledge about what materials/constituents are in the Talcum Powder Products. As such, by turning a blind-eye to the fact that known carcinogens (such as asbestos and/or fibrous talc)

¹⁰ See the PSC’s other memoranda, filed contemporaneously herewith, addressing the constituents of Talcum Powder Products. Further, the PSC understands that Defendants plan to move to exclude each of the PSC’s experts including Drs. Longo and Rigler. As will be demonstrated in the PSC’s opposition to those motions, it is clear that Johnson & Johnson’s Talcum Powder Products contain asbestos and fibrous talc which are known human carcinogens.

exist in Johnson & Johnson's Talcum Powder Products, they can then leap to the litigation conclusion for which they were hired to give – that there is no causal connection between the use of Talcum Powder Products and ovarian cancer.

As made clear above, Johnson & Johnson's Talcum Powder Products contain known and possible carcinogens.¹¹ The only way Defendants' experts could express their litigation opinions of a lack of biological plausibility was to ignore the constituents in Talcum Powder Products. The record shows that Defendants' experts were not permitted to know, let alone assume, that asbestos and/or fibrous talc exist in the Talcum Powder Products, for example, because such a fact, either known or assumed, would totally undermine their opinions that Talcum Powder Products cannot cause ovarian cancer. Defendants' experts view is myopic and as such, inherently unreliable, because they have been blinded to the fact that carcinogens have been constituents of Johnson & Johnson's Talcum Powder products for decades.¹²

Defendants' experts were faced with a paradox - that they reconciled simply by ignoring the constituents of Talcum Powder Products. Had they known, or even assumed the facts, they would have precluded from offering the opinion that

¹¹ See *infra* at 20, esp. at fns. 29-30.

¹² See January 16, 2019 Expert Report of William E. Longo, PhD and Mark W. Rigler, Ph.D.

asbestos, for example, in Talcum Powder Products cannot cause ovarian cancer (because it is contrary to the generally accepted scientific evidence). But not knowing or ignoring the facts also precludes them from offering an opinion that Johnson & Johnson's Talcum Powder Products cannot cause ovarian cancer because their lack of knowledge of its constituents renders such an opinion unreliable.

Moreover, while biological plausibility is one aspect of the causal relationship analysis that Sir Austin Bradford Hill discussed in his causation lecture¹³ the value of any assessment of plausibility in the causation analysis is limited by the science of the day.¹⁴ Indeed, even one of Defendants' experts in this litigation, Dr. Christian Merlo, has conceded that biological plausibility is of limited importance.¹⁵

Thus, the value of the opinions of Defendants' four molecular biologist experts is marginal, considering the lack of importance of biological plausibility to the general causation analysis and the inherent lack of reliability of their opinions.

¹³ Sir Austin Bradford Hill, *The Environment and Disease: Association or Causation*, in 58 Proc. Royal Soc. Med. 295-300 (1965) ("Hill article"), attached as **Exhibit K**.

¹⁴ *Id.* at 298: ". . . this is a feature I am convinced we cannot demand. What is biologically plausible depends upon the biological knowledge of the day."

¹⁵ February 25, 2019, Expert report of Christian Merlo, PhD, MPH ("Merlo Report") at 43, attached hereto as **Exhibit L**. Dr. Merlo lists plausibility as one of the nine aspects of a causal relationship, as articulated by Bradford Hill, but does not discuss it further, instead noting: "In my discussion below, I focus on three criteria – strength of association, consistency of association and biologic gradient – that are the most relevant to my opinions and experience as an epidemiologist."

Their litigation-driven goal was to elevate the importance of biological plausibility above other Bradford Hill criteria, where it is recognized that biological plausibility does not have such stature, and even if it did, a proper analysis of biological plausibility would require knowledge of the components of the products involved.

Defendants' witnesses attempt to overcome the defect of not knowing the composition of the Talcum Powder Products by relying on epidemiology to fill the void. But they lack expertise in that discipline, which further taints the reliability of their opinions.

While an epidemiologic assessment does not require knowledge of the materials comprising the substance in question, the same is not true for expert opinions that are ultimately directed at the molecular mechanism by which that substance does or does not act. It is wholly unreasonable – and unreliable – for a molecular biologist or molecular geneticist to offer an opinion on the plausibility (or lack thereof) of the mechanism by which an alleged carcinogen acts, when the expert has not even identified the carcinogens or possible carcinogens in question. Moreover, to rely on epidemiology, the witness must have expertise in the discipline. These experts do not.

There are certain additional gaps in the methods and reliability of the opinions of these witnesses, which are unique to each witness and addressed more fulsomely below.

Finally, as to Dr. Shih, he also seeks to utilize a “Study” that he is in the process of conducting to further support his opinions.¹⁶ However, this “Study” is in the interim stages, and as will be discussed in *Section IV.D.* of this Memorandum, *infra.*, his opinions related to the Study are unreliable and therefore should be excluded.

III. LEGAL STANDARD

The PSC incorporates as if set forth in its entirety the legal standard set forth in its *Omnibus Brief Regarding Daubert Legal Standard and Scientific Principles for Assessing General Causation* (“*Omnibus Brief*”) as supplemented herein.

IV. ARGUMENT

A. THE OPINIONS OF DRS. SHIH, NEEL, BOYD AND BIRRER RELATING TO BIOLOGICAL PLAUSIBILITY SHOULD BE EXCLUDED BECAUSE THESE EXPERTS EXPRESSED THEIR OPINIONS WITHOUT HAVING ANY INFORMATION ABOUT THE CONSTITUENTS OF TALCUM POWDER PRODUCTS, PARTICULARLY WHETHER THEY CONTAIN KNOWN CARCINOGENS

The first, and primary, reason why the opinions of Drs. Shih, Neel, Boyd and Birrer are unreliable is that they offer their opinions about the biological inertness of Johnson & Johnson’s Talcum Powder Products, despite having no idea what constituents are found in those products.

¹⁶ Dr. Shih has attached his incomplete Study to his Expert Report in this case an apparent effort to bolster his opinions.

As a preliminary matter, it is important to be clear about what “biologic plausibility” means within the Bradford Hill guidelines. It is not “proof of mechanism” as these witnesses suppose. Rather, this Hill aspect—which Hill stated need not be present for a causal inference to be made—allows for an assessment of the biologic evidence to see whether it “makes sense” that the association that is seen is indeed causal.¹⁷

For these molecular scientist to express an opinion regarding the nature of the Talcum Powder Products, they must first understand the composition of the product to determine whether it is biologically plausible. Their area of science is not like epidemiology, which is a study of population-level data, but one of composition – the chemicals and elements that make-up the agent. Thus, while in epidemiology it may not be necessary to know or have an opinion about the molecular composition of a putative causative agent to establish a causal *association*, because all that is involved is an analysis of population reports, that indulgence does not apply to the opinions of molecular biologists or molecular geneticists.

In other words, it is entirely appropriate for a scientist to apply talc or Talcum Powder Products to tissue cultures without knowing the molecular composition of the talc, and then to offer an opinion on biological activity. Similarly, it is entirely appropriate for a scientist either to form an opinion or to make an explicit assumption

¹⁷ See fn. 8, *supra*. and the PSC’s *Omnibus Brief* at II (F), page 34.

about whether Talcum Powder Products contain, for example, asbestos, fibrous talc, or heavy metals, and then to offer an opinion on their biological activity. What is not appropriate is to be agnostic to the composition of Talcum Powder Products with respect to known carcinogens. For these experts to express a causation opinion that the Talcum Powder Products are inert and cannot cause cancer, regardless of what materials might or might not be in them, is unsupported and unreliable. While these experts do not know what the constituent substances are in Talcum Powder Products, they express with “reasonable scientific certainty” that whatever those substances are, at a molecular level, they cannot cause cancer. This is a wholly unreliable opinion that should be excluded.

Without grounding in either experiment or generally-accepted scientific knowledge, these opinions are no more than the *ipse dixit* of these witnesses and should be excluded on those grounds. While Defendants’ experts’ training, background, and experience might enable them to assess the strength or weaknesses of experimental results, these experts do not possess what Dr. Shih himself said is “very important. . . to answer whether talc is – is causal or not.”¹⁸

1. Dr. Neel’s Opinions About Biological Plausibility are Not Grounded in Sound Science

¹⁸ Shih Dep., at 67:10–68:1.

Dr. Neel testified that he is not a geologist and has no opinion on the composition of Talcum Powder Products in this case:

Q. So you have no knowledge one way or the other whether fibers occur in talcum powder, and if so, whether there would be any health hazard as a result?

A. . . I am not a mineralogist. I am not a geologist. I have no comment on the composition of talc today or prior to today, like in 2001.¹⁹

Dr. Neel's ignorance of the constituents of Talcum Powder Products is fatal to his opinion²⁰ that the products cannot cause ovarian cancer. As a result, Dr. Neel's opinion is unreliable. As an illustration, if Talcum Powder Products **contain** asbestos and/or fibrous talc, and those materials **can** cause ovarian cancer, then Talcum Powder Products **containing** those materials can also cause ovarian cancer. In essence, Dr. Neel is expressing his opinion in the abstract without regard to whether known or possible carcinogens are in the products. Not knowing the constituents of the product precludes him from providing a reliable opinion about whether the constituents in Talcum Powder Products can cause ovarian cancer.

¹⁹ Neel Dep., at 308:4-18.

²⁰ See, e.g., Neel Report, at 28 ("The plaintiffs' experts' causation theories do not comport with what we know about carcinogenesis generally or the development of ovarian cancer specifically; nor do they have sufficient support from epidemiological research.").

Dr. Neel is indisputably without an opinion on whether asbestos and/or fibrous talc are found in Talcum Powder Products. In addition to the language quoted above, Dr. Neel testified that regarding the experiments in Dr. Mossman's paper: "Yes, they claim that it's non-fibrous talc. But again, *I'm not an expert in mineralogy or geology*. So I can't comment on the quality of their evaluation. But I will say that it's non-fibrous talc, according to the paper."²¹ He also testified:

Q. And even if Johnson & Johnson's Baby Powder and Shower to Shower have – are shown to contain asbestos, that was – reviewing that evidence and that data were not important?

A. No, because the issue is whether there is any compelling scientific evidence that Johnson & Johnson's products, when applied perineally, give rise to an increased incidence of ovarian cancer, and/or whether there was any evidence that Johnson & Johnson products, when applied in experimental animals have any evidence of causing pre- or neoplastic conditions of the ovaries or fallopian tubes. That was the issue that I considered in issuing my report. And therefore, the issue is what's – what the Johnson & Johnson products do, not whether asbestos is involved in ovarian cancer.²²

There is strong evidence – discussed elsewhere in the PSC's experts' reports and Memoranda the PSC is filing in these *Daubert* proceedings²³ – revealing that Johnson & Johnson products *do* contain asbestos, fibrous talc, and other known or possible carcinogens. Evidence of the presence of these carcinogenic substances

²¹ Neel Dep., at 398:4-17 (emphasis added).

²² Neel Dep., at 49:19–50:17.

²³ See fn. 9, *supra*.

provide additional biologic evidence that the association observed between talcum powder products and ovarian cancer is causal – but went wholly unevaluated by Dr. Neel.

Rather than doing the comprehensive review of the whole products that is required, Dr. Neel did “only a very limited amount of review” – and even that was only as to asbestos. As to fibrous talc, a carcinogen which has been shown to be present in 99% of the historical samples that have been tested,²⁴ Dr. Neel did not recall doing *any* review:

Q. You also reviewed the IARC monograph in 2012, correct?

A. Which one is that?

Q. That’s the one related to asbestos.

A. *I looked at that very cursorily. I really didn’t have the time to do an exhaustive study of asbestos and ovarian cancer.* I looked at it cursorily. And several other papers.

* * *

Q. Did you do any *comprehensive* review on fibers and particles and their role in carcinogenesis?

A. **No.**

Q. Did you do *any* literature review on asbestos?

A. **Only a very limited amount of review** of asbestos in the context of ovarian cancer.

²⁴ See January 15, 2019, Expert report of William E. Longo, PhD & Mark W. Rigler, PhD, at 8.

Q. Did you do *any* review on fibrous talc?

A. *Not that I recall.* Only in the context of it might have been mentioned in some of the papers that I reviewed.

Q. *What is fibrous talc?*

A. I can't describe. I'm not a geologist. I'm a cancer biologist.²⁵

Having explicitly failed to consider whether Talcum Powder Products contain materials that can cause ovarian cancer, Dr. Neel's opinion is unreliable under *Daubert* and its progeny and should be excluded in its entirety.

2. Dr. Shih's Opinions About Biological Plausibility are Not Grounded in Sound Science

The same problem that render Dr. Neel's opinions as unreliable regarding a lack of knowledge about the composition of Talcum Powder Products, likewise undermine the opinions of Dr. Shih that there is no biological plausibility that Talcum Powder Products cause ovarian cancer. Dr. Shih also explicitly failed to consider the composition of the Talcum Powder Products and whether they contain known carcinogens, such as asbestos and /or fibrous talc. Dr. Shih was particularly evasive in "answering" questions about this subject:

Q. Do you consider you're an expert in talcum powder products?

A. Could you be more specific for the question?

Q. *Are you familiar with talcum powder products?*

²⁵ Neel Dep., at 49:9-18 and 98:9-99:2 (emphasis added).

A. What do you mean, “familiar with”?

Q. ***Do you know what is in, for example, bottles of Johnson & Johnson talcum powder?***

A. I think you have several questions in a stream. Could you – might go by steps, your question, one by one by one, so I can answer your question more effectively.

Q. ***Do you know what the constituent parts of Johnson & Johnson’s talcum powder is or are?***

A. You mean the Johnson & Johnson’s powder in the market?

Q. Yes.

A. Or in – back to ten years ago, 20 years ago, 30 years ago? What do you mean?

Q. Today.

A. ***Today, I did not see any Johnson & Johnson’s powder.***²⁶

Likewise, Dr. Shih refused to answer questions about the chemical structures of talc and asbestos, admitting that such knowledge is outside his field of expertise:

Q. Doctor, is there a difference in your mind between the chemical structure of talc and asbestos or the structural structure?

A. Structure of the – I’m not a mineralogist.²⁷

²⁶ Shih Dep., at 54:20 – 56:3 (objections omitted, emphasis added).

²⁷ Shih Dep., at 250:7-17 (objection omitted). See, e.g., *id.* at 54:4-19.

Dr. Shih also had no opinion about whether asbestos or fibrous talc are present in Johnson & Johnson's Talcum Powder Products:

Q. Okay. Doctor, do you have an opinion on whether the talcum powder products that we are discussing in this case contain asbestos?

A. ***I don't know.***

Q. Okay. Do you have an opinion as to whether the talcum powder products at issue in this case ever contained asbestos?

A. ***I don't know.***

Q. Do you have an opinion on whether the talcum powder products at issue in this case contain fibrous talc also known as talc in an asbestiform habit?

A. ***This is beyond my expertise*** and you should ask mineralogist and a toxicologist, geologist.

Q. Does that – I'm sorry. Does that mean you don't have an opinion?

A. I already answered my question.

Q. Okay. Do you have an opinion on whether the talcum powder products at issue in this case contain – ever contained fibrous talc, also known as talc in an asbestiform habit?

A. ***Same answer to that previous question.***²⁸

And Dr. Shih had no opinion about whether those materials can cause cancer:

Q. Do you have an opinion on whether asbestos is a known carcinogen?

²⁸ Shih Dep., at 400:10–401:23 (objections omitted, emphasis added).

A. ***I did not study asbestos.***

Q. Do you have an opinion on whether fibrous talc is a known carcinogen?

A. ***I did not study it either.***²⁹

As a result, Dr. Shih's litigation opinion is completely unreliable. If asbestos and/or fibrous talc can cause ovarian cancer (and Dr. Shih has no opinion on whether they do), and if asbestos and/or fibrous talc are present in Defendants' Talcum Powder Products (and Dr. Shih has no opinion on whether they are), then it stands to reason that Defendants' Talcum Powder Products can cause ovarian cancer. In that context, there is simply no reliable basis for Dr. Shih to conclude that Defendants' Talcum Powder Products cannot cause ovarian cancer when he testified he had not studied the subject, *at all*.

However, having been painted into this corner, Dr. Shih then attempted to rehabilitate himself by testifying that he did have an opinion on these issues that he had not studied. Having just been asked if asbestos is a known carcinogen and testifying in response that he "did not study asbestos" and having been asked about fibrous talc and testifying that "I did not study it either," Dr. Shih went on to testify that in his opinion, asbestos and/or fibrous talc are not carcinogenic for ovarian cancer, after all:

²⁹ *Id.* at 402:1-10 (objection omitted, emphasis added).

Q. Do you have an opinion on whether asbestos can cause ovarian cancer?

A. ***There is no credible science and cogent evidence.*** If you have one, please show it to me.

Q. Do you have an opinion on whether fibrous talc, also known as talc in an asbestiform habit, can cause ovarian cancer?

A. You asked me several times.

Q. No.

A. Same answer.³⁰

It is the epitome of the “*Hear No Evil, See No evil, Speak No Evil*” approach:

Dr. Shih claims no knowledge as to whether asbestos and/or fibrous talc is carcinogenic because he “did not study” them, but then (having not studied them) asserts that there is no “cogent evidence” that they can cause ovarian cancer. Of course, someone who doesn’t study them is not going to be aware of the IARC monographs³¹ classifying both asbestos and fibrous talc as Group I carcinogens for which there is a causal connection with ovarian cancer.³²

This is not the reliable, methodical testimony of an expert. It is pure, fact-free conclusory advocacy without any methodology to support the testimony. As Judge Learned Hand wrote nearly a century ago, “Argument is argument, whether in the

³⁰ Shih Dep., at 402:11–403:4 (objections omitted).

³¹ IARC 2012.

³² IARC 2010.

[witness] box or at the bar, and its proper place is the last.” *Nichols v. Universal Pictures Corp.*, 45 F.2d 119 (2d Cir. 1930). Accordingly, Dr. Shih should be precluded entirely from testifying in this case.

3. Dr. Boyd’s Opinions About Biological Plausibility are Not Grounded in Sound Science

The same flaws regarding composition, which undermine the opinions of Dr. Neel and Dr. Shih, likewise undermine those of Dr. Boyd: he too has failed to consider whether known carcinogens are constituents of Johnson & Johnson’s Talcum Powder Products. As a result, his *ipse dixit* opinion that those products are inert and harmless is unreliable and should be excluded:

Q. ***Have you ever studied*** the effect of asbestos in the human body?

A. ***No.***

Q. Do you have an opinion as to whether or not there’s asbestos present in any Johnson & Johnson talcum powder product?

A. Could you please repeat the question?

Q. ***Do you have an opinion*** as to whether or not there is asbestos present in any Johnson & Johnson talcum powder product?

A. ***No.***

Q. ***Do you have an opinion*** as to whether or not there is any fibrous talc present in any Johnson & Johnson talcum powder?

A. ***Again, if we’re referring to Johnson’s baby powder***, the answer would be ***no.***

Q. Do you know if there are any other suspected carcinogens known to be within the fragrant chemicals that can be found in Johnson & Johnson baby powder – or talcum powder?

A. *I have no opinion.*³³

Yet, having testified that he, in fact, really did not know the constituents of Defendants' Talcum Powder Products, specifically whether they contained asbestos or fibrous talc or other suspected carcinogens, when asked if he would change his opinion if he knew of the presence of carcinogenic ingredients, Dr. Boyd said such information would not change his opinions:

Q. If there were asbestos in Johnson & Johnson's talcum powder, would that change *any* of your opinions that you had formulated within your expert report?

A. My opinions are based on Johnson's baby powder, the use of Johnson's baby powder.

* * *

Q. Okay. Do you agree with Dr. Roberta Ness and Carrie Cottreau when they describe asbestos as an additional risk factor for ovarian cancer?

A. Well, if I'm not offering an opinion, *I'm not going to offer an opinion* on someone else's opinion.³⁴

Dr. Boyd's admitted failure to "study[] the effect of asbestos on the human body" did not prevent him from asserting it has no link to inflammation or ovarian cancer, in contravention to peer-reviewed, published articles:

Q. Okay. So now they state, "Ovarian cancer has been linked to several events and conditions which are related to inflammation and repair, including incessant ovulation, endometriosis, *exposure to talc and asbestos*, and in some cases pelvic

³³ Boyd Dep., at 75:21–76:24 (objections omitted, emphasis added).

³⁴ *Id.* at 78:13-19, 193:5-19 (colloquy omitted, emphasis added).

inflammatory disease.” Do you disagree that the ovarian cancer has been linked to several events and conditions which are related to inflammation?

A. It depends.

Q. Upon?

A. What type of inflammation and in what context. ***What type of ovarian cancer...³⁵***

But when asked about what type of ovarian cancer it depended upon, Dr. Boyd could not actually say:

Q. ***Can you list for us today as you sit here the different types of ovarian cancer?***

A. Broadly speaking.

Q. Specifically speaking?

A. ***Well, that's an impossible question to answer.*** Are you talking about histologic subtypes, or are you talking about epithelial ovarian cancers versus sex cord stromal tumors and germ cell tumors? I mean, what –

Q. Well, the first – the last ones you described are different forms of histologic subtypes, correct? So to make it easy for you, one you're –

A. You don't need to make it easy for me. ***I'm pretty familiar with the subtypes of ovarian cancer.***

Q. Okay. ***Which form of ovarian cancer has not been linked to chronic inflammation?***

A. ***That's frankly a ridiculous question.***

³⁵ Boyd Dep., at 211:20–212:12 (emphasis added).

Q. Is that so? Can I assume that you can't answer that?

A. I did answer.

Q. Do you know the answer to it?

A. *I'm saying it's impossible to answer* a ridiculous question, in my mind.³⁶

Dr. Boyd failed to “study[] the effect of asbestos on the human body,” failed to consider whether the presence of a known carcinogen like asbestos in Johnson & Johnson’s Talcum Powder Products could make them carcinogenic, but then suddenly did know enough about asbestos to deny that it is linked with ovarian cancer and inflammation. Such opinion testimony in the presence of a plethora of peer review published articles in scientific journals to the contrary clearly demonstrates the lack of reliability of his opinions.³⁷

This is not the methodical, reliable testimony of an expert witness; it is the opinion of a zealous partisan being paid \$1,200 an hour for his testimony.³⁸ As a result, and as with Drs. Neel and Shih, Dr. Boyd’s failure to consider whether known carcinogens may be constituents of Defendant’s Products means that his opinions

³⁶ Boyd Dep., at 213:2–214:19 (colloquy and objection omitted, emphasis added).

³⁷ IARC Monograph 100c, at 219, 253-257.

³⁸ Boyd Dep., at 18:1-3, 16-19 (“Q. And you’re charging \$1,200 per hour for deposition and other testimony? A. Yes. . . . Q. Okay. When did you start charging \$1,200 an hour? A. Well, at the beginning of this proceeding.”).

regarding the carcinogenicity of those products are neither reliable nor the product of a sound methodology, and therefore must be excluded in their entirety under *Daubert* and its progeny.

4. Dr. Birrer's Opinions About Biological Plausibility are Not Grounded in Sound Science

The same defect that undermine the opinions of Drs. Neel, Shih, and Boyd, regarding absence of knowledge of the constituent ingredients of the Talcum Powder Products, likewise undermine those of Dr. Birrer: he too has failed to consider whether known or possible carcinogens are or are not components of Johnson & Johnson's Talcum Powder Products. Dr. Birrer fails to meet *Daubert* standards for any opinions that he might offer relating to the presence or role of asbestos, fibrous talc, or any other components of talcum powder products and their association with ovarian cancer. As a result, his opinion regarding whether the Talcum Powder Products are inert and harmless is unreliable and should be excluded.

Dr. Birrer is not an expert in asbestos: "Well, as I said, I'm not a[n] asbestos expert"³⁹; "I'm not going to go down the line of being an expert in asbestos."⁴⁰

Similarly, he is not an expert on mechanisms by which asbestos causes cancer:

Q. What's your understanding of the mechanism by which asbestos causes cancer?

³⁹ Boyd Dep., at 71:3-4.

⁴⁰ *Id.* at 54:15-16.

A. Again, I'm not necessarily an expert on this⁴¹ Moreover, Dr. Birrer "wasn't asked to evaluate the role of asbestos in ovarian cancer"⁴² hence he offers no opinions regarding asbestos, fibrous talc, heavy metals, fragrance chemicals, or any other components of Johnson's talcum powder products in his expert report.

Dr. Birrer's admitted ignorance about asbestos *per se* extends to lacking even basic knowledge of the significance of particles and fibers, a key element in understanding the biological action of minerals like talc and asbestos. ("Q. Do you know what fibrous talc is? A. I'm not sure I can really define it.")⁴³; and ("Q. Is it important whether the substance in Johnson's baby powder and Shower-to-Shower is in particulate form or in fiber form? A. I don't know.").⁴⁴

The absence of a reliable methodology underlying his opinions is readily apparent: Dr. Birrer did not perform a comprehensive literature review for asbestos and ovarian cancer, fibrous talc and ovarian cancer, heavy metals and ovarian cancer, or fragrance chemicals and ovarian cancer.⁴⁵ He is not aware of an IARC Monograph

⁴¹ *Id.* at 299:23-24.

⁴² Birrer Dep., at 57:11-12.

⁴³ *Id.* at 262:3-4

⁴⁴ *Id.* at 56:2 –57:3.

⁴⁵ *Id.* at 107:17-24, 108:14-21.

covering talc containing asbestos or asbestiform fibers,⁴⁶ nor did he look at the IARC Monograph sections on nickel, chromium, or cobalt.⁴⁷ He was unaware of Dr. Michael Crowley's expert report on fragrance chemicals, and consequently did not read the report.⁴⁸

Dr. Birrer also lacks expertise and knowledge regarding the composition of Johnson's talcum powder products:

A. But in terms of the compositional analysis of talcum powder, *that is not within the area of my expertise, and the various forms of asbestos in talc* in terms of mineralogy *is not something I've spent time on.*

* * *

Q. And what is contained in the Johnson's baby powder, to your understanding?

A. Talc. And I know that's an issue that's coming up in terms of are there other things. I mean, clearly there are other things that – the *product smell nice, so there must be some fragrance...* But I don't know of any – first of all – *that's not my area of expertise...*⁴⁹

⁴⁶ *Id.* at 69:15-19 (“Q. [T]here's a different IARC monograph published in 2012 that would cover talc containing asbestos or talc containing asbestiform fibers, correct? A. I don't think I've seen that.”); *see* IARC Monograph 100c (2012).

⁴⁷ Birrer Dep. at 70:17-19.

⁴⁸ *Id.* at 87:21-88:12.

⁴⁹ Birrer Dep., at 57:15-19, 84:5-18 (emphasis added to both).

Dr. Birrer's opinions on the issue of biological plausibility should be excluded since he lacks fundamental information regarding the constituents of the Talcum Powder Products or whether those constituents can cause ovarian cancer.

B. DRS. SHIH, NEEL AND BOYD ARE NOT QUALIFIED IN EPIDEMIOLOGY YET EACH RENDERED OPINIONS REGARDING EPIDEMIOLOGICAL STUDIES IN AN ATTEMPT TO BOOTSTRAP THEIR UNRELIABLE OPINIONS THAT IT IS NOT BIOLOGICALLY PLAUSIBLE THAT TALCUM POWDER PRODUCTS CAN CAUSE OVARIAN CANCER

Drs. Shih, Neel and Boyd are not qualified to testify regarding the strengths and weaknesses of epidemiological studies. Understanding that the law recognizes that "most arguments about an expert's qualifications relate more to weight to be given the expert's testimony than to its admissibility[,]” *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782 (3d Cir. 1996), the law still requires that an expert witness have some specialized expertise on the particular subject at issue in a case in order to offer an opinion in that area. *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008). Molecular scientists are typically not trained or experienced to interpret or rely on epidemiological studies to assess whether a substance is carcinogenic. Therefore, they should be required to demonstrate they possess unique expertise that is outside their scientific discipline, as a condition to being permitted to offer the opinions expressed in this case.

In their expert reports, Drs. Shih, Neel and Boyd venture far outside their area of expertise to give opinions about the relative strengths and weaknesses of the epidemiological studies relied on by the PSC's epidemiology experts.⁵⁰ They have also relied, in part, on the results of the epidemiology studies – for their opinions about the lack of a *molecular* mechanism. These witnesses have bootstrapped epidemiology – a science beyond their areas of molecular expertise – and have relied on their flawed and faulty analysis to discredit the PSC's evidence of causation. Accordingly, their opinions should be excluded in their entirety.

1. Dr. Neel is Not an Epidemiologist, Yet Utilizes Epidemiology to Attempt to Overcome the Fact That His Opinions Are Unreliable Because He Has No Knowledge of the Constituents of Talcum Powder Products

Dr. Neel is not an epidemiologist and did not perform an appropriate causation analysis in this case:

Q. Did you perform a Bradford Hill analysis to determine causation in this case?

A. Well, *I'm not an epidemiologist. Bradford Hill criteria are epidemiological criteria.* I did, you know, read – in the course of doing my research, I did read the Bradford Hill paper, and I did address several of the issues that Bradford Hill addressed. But,

⁵⁰ The PSC is moving against Defendants' epidemiologists and will be opposing Defendants' motions attacking its epidemiologists. To the extent more explicit information is required by the Court relating to the infirmities in the opinions of these non-epidemiologists about epidemiology, the PSC incorporates those papers discussing the science of epidemiology.

you know, *as I said, my – my expertise, as I think you know, is primarily in the area of cancer biology.*⁵¹

Dr. Neel admitted that he has never performed a Bradford Hill analysis in his career as a cancer biologist.⁵² Further, Dr. Neel conceded that, although he “did read the Bradford Hill paper,” he is not an expert in epidemiology and the focus of his opinions was whether or not there is credible evidence that talcum powder can cause ovarian cancer on a cellular and molecular level.⁵³

His lack of training and expertise in epidemiology – including the fact that outside of the courtroom, he does not hold himself out to be an epidemiologist and has not, to date, offered a Bradford Hill analysis – did not stop Dr. Neel from relying on epidemiological papers in coming to his opinion in this case:

Q. So studies that were – would address asbestos and ovarian cancer are not relevant?

A. Not insofar as I can tell. Because I was looking at the issue of Johnson & Johnson products and/or talc as defined by the authors of the papers that used these materials, and/or the authors of *the epidemiological studies that studied this issue on – in offering my opinion.*

Q. And you are talking about the epidemiological studies, correct?

A. No. *I'm talking about the epidemiological studies which used certain things.* And then I'm talking about the bio – biological studies such as they are, that used various forms of talc, whether

⁵¹ Neel Dep., at 104:2-15 (emphasis added).

⁵² Neel Dep. at 105:11-14.

⁵³ *Id.* at 104:21–105:9 and 203:1-12 (emphasis added).

it's Johnson – in some case it's Johnson & Johnson products directly. In other cases, talc from suppliers like – chemical suppliers like Sigma. And each study is different. But the – the studies that I cited in my report all used various forms of “talc” and that's what I considered in offering my opinion.

* * *

Q. Are you aware of an epidemiological study that actually refers to what actual product was used by the women included in the study?

A. My recollection is several said Johnson & Johnson's products. *But we'd have to go through all of the 24-case-control [epidemiological] studies and three cohort [epidemiological] studies that I looked at.*⁵⁴

Dr. Neel's general lack of experience evaluating epidemiological studies coupled with the fact that he has never performed a Bradford Hill analysis undermines Dr. Neel's qualification to offer an opinion on epidemiology.

Even worse is the fact that Dr. Neel compounded his error by then applying the wrong standard to the general causation aspect of his opinion. In contrast to Bradford Hill's well-accepted epidemiological framework,⁵⁵ Dr. Neel seeks to create a new standard: “But for, you know, a series of epidemiological associations which

⁵⁴ Neel Dep., at 47:4–48:7 and 48:20–49:4 (emphasis added).

⁵⁵ Hill article, at 299 (“What I do not believe . . . is that we can usefully lay down some hard-and-fast rules that *must* be obeyed before we accept cause and effect. None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as the *sine qua non.*”); *see also* the PSC's Omnibus Brief at 17.

are conflicting and weak, the biological plausibility becomes essential.”⁵⁶ This testimony incorrectly elevates the importance of biological plausibility, contrary to Bradford Hill. Dr. Neel also suggested that: “I think that the general standard for a cancer biologist to accept causation would *require* experiments in 2019. And I state that as an editor – a member of the editorial board of six journals, including the two most prominent cancer biology journals.”⁵⁷

However, not one of those journals is in epidemiology, nor is Dr. Neel a member of NYU’s epidemiology department.

Unfortunately, Dr. Neel’s opinion simply reflects the biases of a career as a cancer biologist: it is unsurprising that he feels that his area of study is “essential” to determining the issue of causation. But that is not the opinion of most epidemiologists – including one of Defendants’ proffered experts, Dr. Merlo, who notes in his report that “I focus on three criteria – strength of association, consistency of association and biologic gradient – that are the most relevant to my opinions and experience as an epidemiologist.”⁵⁸ Conspicuous by its absence from Dr. Merlo’s

⁵⁶ Neel Dep., at 148:21–149:1.

⁵⁷ Neel Dep., at 149:6-13 (emphasis added).

⁵⁸ Merlo Report, at 43.

list of the “most relevant” aspects of a causal relationship is the biological plausibility that Dr. Neel says is essential.⁵⁹

Further, it is widely accepted that far from being “essential,” biological plausibility – like all aspects of a causal relationship – is simply one aspect among many. As one of Defendants’ proffered experts in epidemiology explains about aspects of a causal relationship:

[N]one is required as essential or absolutely necessary. They can simply help to provide a framework to guide epidemiologists to decide whether or not there is another more likely way of explaining the association, including non-causal explanations for the results of individual studies.⁶⁰

Regardless of whatever qualifications he may have as a cancer biologist, Dr. Neel’s opinion wanders far afield from that subject area. Further, he bases his opinion on an inaccurate understanding of epidemiology; as a result, he is not qualified to offer the opinion set forth in his report. As Dr. Neel admitted he is not an epidemiologist and does not do epidemiological work outside of the courtroom. As such, he is simply unqualified to offer his opinion in this case.

⁵⁹ Indeed, *Dr. Neel’s view appears to be that fellow defense expert Dr. Merlo is not a credible scientist because he does not require proof of mechanism to determine causation*: “If you ask any major scientist in the United States what is the accepted standard for establishing causation, they will tell you a mechanism-based experiment. I don’t think you can find a credible scientist in the world – or in the United States or the world who would say otherwise.” Neel Dep., at 151:20–152:3.

⁶⁰ Merlo Report, at 30 (emphasis added); *accord*, Hill article, at 299 (see fn. 44, *supra*).

2. Dr. Shih is Not an Epidemiologist, Yet Utilizes Epidemiology to Attempt to Overcome the Fact That His Opinions Are Unreliable Because He Has No Knowledge of the Constituents of Talcum Powder Products

Epidemiology is likewise a substantial basis for Dr. Shih's opinions. He testified that "*my opinion is based on my literature search about epidemiology.*"⁶¹ In Dr. Shih's expert report, he discusses and criticizes various epidemiological studies regarding talcum powder in detail, suggesting the "epidemiological studies clearly fail to show an association between talcum powder exposure and women who develop ovarian cancer, including prospective cohort studies."⁶²

Dr. Shih's report discusses the epidemiologic literature in detail, including the Hazard Ratios and Confidence Intervals (HR and CI, respectively) of certain studies,⁶³ yet when asked what a confidence interval is, Dr. Shih replied, "*I am not an epidemiology expert*" and "you should defer those question to them":

Q. Do you know how, when looking at a study that has some degree of epidemiology in it, do you know how to interpret a confidence interval?

⁶¹ Shih Dep., at 112:9-11 (emphasis added).

⁶² Shih Expert Report, at 11.

⁶³ See, Shih Expert Report, at, e.g., 12 ("there was little association between baseline perineal talc use and subsequent ovarian cancer (HR: 0.73, CI: 0.44, 1.2). In this report, douching was more common among talc users (odds ratio: 2.1, CI: 2.0, 2.3), and douching at baseline was associated with increased subsequent risk of ovarian cancer (HR: 1.8, CI: 1.2, 2.8).")

A. Again, I'm a cancer biologist and a gynecology pathologist. I review those articles that is relevant and important and – and related. ***I am not epidemiology expert. You can – you should defer those question to them.*** I can – I am here – okay. This is very important: My job here is served as an expert in cancer biology and gynecology pathology to answer whether talc is – is causal or not.⁶⁴

Similarly, Dr. Shih could not discuss the Bradford Hill aspects of a causal relationship without having the paper in front of him:

Q. Did you conduct an analysis in this case utilizing the Bradford Hill viewpoints on causation?

A. Again, can I have this Brad Hill – Bradford Hill documents before we can further discuss?

Q. . . Do you recall reading at any time in your professional career a 1965 publication by Sir Bradford Hill regarding viewpoints for determining causation?

A. Can I see the viewpoints for our discussion?

Q. I just want to know if you recall seeing that paper.

A. I need to see the paper in order to answer your question.

Q. Do you recall at any time reading a published paper dealing with causation and viewpoints that consisted of, for example, the strength of association, analogy, biological gradient, biological plausibility, analogy, experimentation, and coherence? Do you recall ever seeing any document like that?

MS. MILLER: Objection. Compound.

THE WITNESS: I need to see the documents before we can further discuss.

⁶⁴ Shih Dep., at 67:10–68:1.

Q. Without seeing any document, you can't recall ever reading or seeing a study or publication dealing with viewpoints of causation?

A. I saw the viewpoint, but I need to see documents to see which ones specifically you refer.⁶⁵

While depositions are not a memory test *per se*, no expert in epidemiology needs to have the Bradford Hill paper in front of him or her to know whether he or she ever reviewed the paper. Experts who work with Bradford Hill know that without needing to refresh a recollection. And, an expert who cannot discuss aspects of a causal relationship without having the Bradford Hill paper in front of him⁶⁶ is not qualified to speak to Bradford Hill and epidemiology principles – nor to offer an opinion based even in part thereon.

At times, Dr. Shih was more candid about his lack of expertise in epidemiological matters:

Q. Okay. Sir, do you consider yourself an expert in epidemiology?

A. I am a cancer biologist who focus on – I understand what initiate ovarian cancer, and I am also practicing gynecology pathologist. And I also run – educator to train residents, pathology residents,

⁶⁵ Shih Dep., at 56:4-58:7.

⁶⁶ See also, Shih Dep. at, e.g., 255:15-19:

Q. Now, what Dr. Kane in her report was – are you familiar with the Bradford Hill viewpoint of analogy?

A. Could you show me the Bradford Hill?

post-doc fellows, and the graduate students in ovarian cancer research and diagnosis.⁶⁷

* * *

Q. And by reviewing the published literature dealing with epidemiology, does that give you expertise in epidemiology?

MS. MILLER: Objection.

A. As I said, I reviewed other literatures in order to know better about the issues, about the – what is the origin of ovarian cancer. And it is a background in my study and also in my context.

Dr. Shih never answered the direct question about epidemiological expertise, despite the fact that he testified his opinion is based upon his knowledge and understanding of the epidemiological literature: “my opinion is based on my literature search about epidemiology.”⁶⁸

Further, this literature was significant enough that even different results from the slides that Dr. Shih observed would not have changed his opinion:

Q. Okay. And in looking at more slides is it possible that the results will change that will change your opinion regarding the association of chronic inflammation and the precursor lesions?

A. So – so my opinion as in the Exhibit 2 is not totally dependent on the results. And these results can support some of the important arguments. ***But again, my opinion will not change, even there is a different result in my official publications. My opinion is based on my literature search about epidemiology,***

⁶⁷ Shih Dep., at 52:11-20 and 53:11-22.

⁶⁸ Shih Dep., at 112:9-11.

chronic inflammation, carcinogenesis, molecular genetics, and my 20 years of experience as a scientist and pathologist.⁶⁹

This is a classic illustration of an unreliable method that is no more than a proffered expert's *ipse dixit*. Dr. Shih literally said that his opinion wouldn't change even if the results did. He is wedded to his opinion, regardless of the facts, science, and information. Such an opinion is *not* one that is scientifically reliable but conclusion driven.

That error is magnified by the fact that Dr. Shih's opinion is based in significant part on "my literature search about epidemiology," despite the fact that Dr. Shih also testified that he had no expertise in that field.⁷⁰ Accordingly, Dr. Shih's entire opinion is unreliable under *Daubert* and its progeny and should be excluded on those grounds.

But as with Dr. Neel, Dr. Shih is not one to let his lack of expertise stop him from offering a new standard for causation, which – like Dr. Neel – alters and elevated the biological plausibility aspect of causation (which is one aspect among many of Bradford Hill, not one of which is required) into an absolute and singular requirement for an established molecular mechanism in order to show causation: "any cancer biologist will agree that you need to see the genetic mutation in order to

⁶⁹ *Id.* at 111:2 –112:14 (emphasis added).

⁷⁰ *Id.* at 67:17-18.

establish [a] causal relationship.”⁷¹ There is no basis in law or epidemiological science for adding this requirement; to the contrary, as discussed above, both Bradford Hill and, as set forth above, one of Defendants’ own proffered epidemiological experts agree that no one aspect of a causal relationship is definitive.

Not only is biological plausibility not necessary to show a causal relationship, but biological plausibility is not even one of the more important aspects.⁷² For this additional reason, Dr. Shih’s opinion should be excluded in its entirety.

3. Dr. Boyd Is Not an Epidemiologist, Yet Utilizes Epidemiology to Attempt to Overcome the Fact That His Opinions Are Unreliable Because He Has No Knowledge of the Constituents of Talcum Powder Products

The same defects render Dr. Boyd’s opinions as unreliable. Dr. Boyd also testified that although he had some understanding of epidemiology at a basic level, he is not an expert in that field:

⁷¹ *Id.* at 62:17-23.

⁷² See, e.g., Merlo Report, at 43, and *passim* by its absence; plausibility is mentioned only twice in the entire report – without discussion – and not included in the “most relevant” aspects; accord, November 16, 2018, report of Jack Siemiatycki, Ph.D., M.Sc. (“Siemiatycki Report”) at 64-66, attached hereto as **Exhibit M** (discussing biological plausibility as one of several “Moderately important aspects” and noting the presence of asbestos, asbestiform talc, and heavy metals in Talcum Powder Products).

Q. Would you consider yourself an expert in the epidemiology of ovarian cancer and its associated risk factors?

A. Again, a difficult question to answer. ***I would not consider myself an expert.*** I would say that I'm familiar with *some* of the basic concepts of epidemiologic aspects of ovarian cancer.⁷³

And it was not a difficult question, as Dr. Boyd's later testimony on that subject reveals:

Q. If you're not understanding what the epidemiological principles may be, would you defer to an epidemiologist?

A. I might defer to anyone on any given day about any given topic that had to do with ***a field of inquiry in which I'm not an expert.***

Q. Okay. Are you an expert in the epidemiological principle of effect modification?

A. No.

* * *

Q. Okay. Has your research ever focused on the epidemiology regarding chronic inflammation and the development of cancer?

A. No.⁷⁴

As with Dr. Neel and Dr. Shih, Dr. Boyd did not let his lack of expertise in epidemiology prevent him from imposing a new elevated standard of causation – in

⁷³ Boyd Dep., at 52:19–53:3 (emphasis added, objection omitted).

⁷⁴ *Id.* at 54:4-18; 82:13-17 (objections omitted, emphasis added).

Dr. Boyd's view, "causal association" is an oxymoron. Notwithstanding the success of epidemiology in finding causation unknown to the biological science of the day, from fetid water causing cholera to tobacco smoke causing lung cancer and heart disease, in Dr. Boyd's opinion, epidemiological studies are incapable of showing causation:

Q. Has the causal association between DES and clear cell adenocarcinoma ever been established in a cohort observational study?

A. Well, first of all, you're using the words "causal" and "association" together, which in my mind are different concepts. As I believe I suggested before, in my mind, epidemiologic studies, whether they be case-control or cohort studies, are typically relied upon to suggest associations leading to hypotheses that may be further tested regarding causation. So juxtaposing "association" and "causation" in the [same] sentence is, in my mind, inappropriate.

Q. Has the causal relationship between DES and clear cell adenocarcinoma ever been established in a cohort observational study?

MS. MILLER: Objection. It's a misleading question.

THE WITNESS: I would say no because – for the primary reason that the – the events were extraordinarily rare, and DES was on the market for pregnancy support for a relatively short period of time, late '40s until 1971. It would be impossible to do such a study, in my mind, and have it significantly powered; hence the reliance on animal models over the years to provide much more rigorous evidence of causality with respect to DES and carcinogenicity.

Q. In fact, the initial association between DES and clear cell carcinoma – adenocarcinoma in the offspring of women who took it, the drug, were established in case-control studies initially, correct?

A. I'm of the – I'm aware of the paper that I referenced earlier as being the first suggestion that there was an association.⁷⁵

But when faced with questions he did not want to answer, Dr. Boyd remembered that he is not, in fact, an expert in epidemiology:

Q. Would you agree it would be inaccurate for anyone to say that causation cannot be established for the use of case-control studies?

A. Several negatives in there. Could you repeat the question, please?

Q. Would you agree it would be inaccurate for one to say that a causal association between a substance or a drug and the development of cancer cannot be established through case-controlled, observational epidemiology?

A. ***Well, first, I'm not an expert in epidemiology*** and the – I'll stop there.⁷⁶

And yet while being “not an expert in epidemiology” prevented Dr. Boyd from answering questions about case-control studies, it did not stop Dr. Boyd from opining on the epidemiological data associated with perineal talc use:

Q. Doctor, sitting here today in 2019, in addition to age over 45, no tubal ligation, no breastfeeding, no live births, oral contraceptive use, Jewish ethnicity, family history of ovarian cancer, early onset of breast cancer, would you add long-term genital talcum powder to the list of risk factors for the development of cancer, ovarian cancer?

⁷⁵ *Id.* at 123:4–125:1.

⁷⁶ *Id.* at 125:2-21 (emphasis added, objection omitted).

A. No.

Q. And why is that?

A. It's twofold. *At best, the epidemiologic association is quite weak*, and no biological plausibility.⁷⁷

This is completely improper. A witness cannot avoid those questions he dislikes claiming he's not an expert in the field of the question, but then answer other questions and assert expertise in the same field. Even if, at a *Daubert* hearing, Dr. Boyd were to change his mind again, and decide that he is actually an expert in epidemiology after all, the PSC's have been denied the opportunity to examine the full extent of Dr. Boyd's opinion on the issue, and at a minimum would have to be allowed to re-take Dr. Boyd's deposition and re-brief the *Daubert* issue.

Further, as illustrated above, Dr. Boyd's belief that "the epidemiologic association is quite weak" is integral to his opinion as a whole. As such, it is not severable from the subject matter he claims to be expert in, "many years" of "molecular genetic and genetic research."⁷⁸ Accordingly, the appropriate remedy is instead to exclude Dr. Boyd's testimony in its entirety.

⁷⁷ *Id.* at 144:7-20 (emphasis added).

⁷⁸ *Id.* at 83:5-7.

C. DR. BOYD HAS NO QUALIFIED OPINION ON TALC MIGRATION

Dr. Boyd's expert report makes several assertions about the issue of talcum powder migrating from the perineum to the ovaries. For example, in his report, Dr. Boyd asserts that "the evidence that *any* talc can reach the ovaries from external perineal use is weak"⁷⁹ and that "the same mechanisms of expulsion of talc from areas of the female reproductive tract distal to the ovaries (vagina, cervix, uterus, fallopian tubes) should also prevent talc from otherwise migrating—like a salmon upstream—through this wash of bodily fluids, eventually reaching the ovaries."⁸⁰

However, Dr. Boyd testified at deposition that he is not an expert on the issue of migration of talcum powder to the ovaries and does not intend to offer an opinion in that area:

Q. Dr. Boyd, do you intend to offer an opinion as to whether or not talc powder particles can migrate to the ovaries?

A. **No.**

* * *

Q. And are you an expert in the migration of external particles from the environment to the vagina to the fallopian tubes and/or ovaries?

⁷⁹ Boyd Report, at 4.

⁸⁰ *Id.* at 5.

A. **No.**⁸¹

Accordingly, he should be precluded from testifying regarding whether talcum powder can migrate to the ovaries.

D. DR. SHIH SHOULD NOT BE PERMITTED TO EXPRESS OPINIONS BASED ON HIS INCOMPLETE INTERIM “STUDY REPORT”

Dr. Shih is in the process of conducting a histopathological study entitled, ‘**Study Report to Determine Whether Chronic Inflammation Causes Ovarian Cancer**’⁸² (“Study”), the hypothesis of which is:

if ovarian cancer development is caused by chronic inflammation from various etiologies, one should observe at the human tissue level that the very early lesions of ovarian cancer, i.e., ovarian cancer precursors (before ovarian cancer arises), should be accompanied by chronic inflammation in close geographical proximity to the precursor lesions.⁸³

The Study is not complete and has not been submitted for publication or peer review.⁸⁴ Dr. Shih attached a preliminary draft interim report from the Study to his

⁸¹ Boyd Dep., at 111:4-7 and 253:13-17 (emphasis added).

⁸² See “**Study Report to Determine Whether Chronic Inflammation Causes Ovarian Cancer**,” attached to Exhibit F at page 24?

⁸³ Shih Study Report attached to Exhibit F at 24, 1st full paragraph.

⁸⁴ Shih Dep., at 78: 6-8 (Study Report is incomplete, has not been submitted for publication and, therefore, has not undergone peer-review as of the time of Dr. Shih’s deposition on March 26, 2019).

Rule 26 Expert Report.⁸⁵ Notwithstanding the fact that the Study is not yet finished, Dr. Shih relies on it to opine that “...chronic inflammation observed in ovarian cancer is most likely a result of cancer, not the cause.”⁸⁶ It is not surprising that Dr. Shih’s Expert Report was not submitted for publication; Expert Reports often are not. But what is surprising in that in his Expert Report, Dr. Shih describes his Study Report as, “the final answer” on inflammation in cancer initiation and progression.⁸⁷

Dr. Shih has put the cart-before-the-horse by relying on a Study that he has not yet finished. A hypothesis is an educated guess, it is not an answer and cannot provide the foundation for an expert opinion under *Daubert*. See *Colon v. Abbott Labs.*, 397 F.Supp.2d 405, 415 (E.D.N.Y. 2005) (excluding expert’s opinion as unreliable because it was based on a hypothesis from an incomplete study). Dr. Shih should be precluded from testifying about the Study and his opinions based on it because:

1. it is neither final nor complete;
2. it has no written methodology; and,
3. it does not include contemporaneous notes (which, given Dr. Shih’s inability to remember at deposition basic facts like whether he was the person who wrote the numbers on the

⁸⁵ See Expert Report, at 15 (“My recent study, which is included in full at the end of this report, offers significant support....”) – except, as discussed in the main text *infra*, it is both interim and incomplete. Dr. Shih’s entire Expert Report.

⁸⁶ See Shih Expert Report at 15, 1st full paragraph.

⁸⁷ Shih Expert Report, at 28.

pathology slides he was examining,⁸⁸ is an unreliable methodology that calls into serious question the validity of his results).

Fed. R. Civ. P. (“Rule”) 26(a) (2) (B) (i)-(ii) sets forth the requirements of an expert report. Expert reports “**must** contain: (i) a **complete** statement of all opinions the witness will express and the basis and reasons for them; and (ii) the facts or data considered by the witness in forming them.” (emphasis added).

Dr. Shih testified that Study Report attached to his Rule 26 Expert “is not [a] full report”⁸⁹ and that it will change in its final form, at least in part because a discussion of the limitations and methodology of his work was omitted: “**it is by no**

⁸⁸ Shih Dep., at 177:4-7 (“Q. Is that your labeling system or the way the slides were labeled in the tissue – in the slide bank? A. **I cannot remember that.**”); Shih Dep at 180: 9-13 (“Q. I still don’t understand who came up with that case ID number, you or was it an existing ID number? A. **I cannot recall.**”)(emphasis added to both).

An examination of the slide numbers in Table 2 to the Study Report, Ex. F at 29, reveals that they are neither consecutive nor do they follow a consistent pattern: Study Lesions 1-7 are from Case ID’s S80001-07; Study Lesions 8-16 are from Case ID’s 10150-10144 (in decreasing order); Study Lesions 17-25 are from Case ID’s 10142-33 (also in decreasing order, but omitting some numbers); Case ID’s for Study Lesions 26-55 all begin 10-, except for Study Lesions 38-39, 41-42, and 49-50; and Study Lesions 56-59 have Case ID’s 20001 NFT - 20001 NFT.

In short, they bear every indication of being pre-assigned Case ID numbers from an existing library of tissue slides.

Considering the idiosyncrasies of this slide-numbering format, it is astonishing that three months after examining them, Dr. Shih cannot remember if he created the Case ID numbers or if they were already present when he examined the slides; but given his inability to recall that sort of basic detail, it is imperative that he took contemporaneous notes of his examination.

⁸⁹ Shih Dep. at 100:19.

means that this will be the final publication report,” but “*when I draft the manuscript*, definitely like in other publication I did, *I will use the term to show the limitation*, but not necessarily using the term, the word of limitation in the study outcome.”⁹⁰

Regardless of whether that exact word is used, omitting any discussion of the “limitations” of his opinion from the incomplete report is, of course, in violation of Rule 26(a)’s requirement that it be a summary of *all* of the witness’s opinions – not just the parts that are helpful to the proffering party.

Instead, Dr. Shih testified that his Study Report currently *lacks* key aspects of a Rule 26 report, including a description of the “***methodologies***” employed and the aforementioned discussion of the ‘limitations’ of the Study:

Q. Is it your testimony today that the – your recent study we’ve been discussing is *not* the full report but is going to be modified?

MS. MILLER: Objection.

A. This is the data I have, but when you wrap up a study, you have **other ingredients, like introduction, methodologies, result, discussion. This is not full report as a publication.** I mean a full report meaning its publication. Okay. **But this is a full result I have at this moment.**⁹¹

⁹⁰ *Id.* at 98:10-24 and 99:1-2.

⁹¹ *Id.* at 100:9-23 (emphasis added).

Thus, Dr. Shih would have this Court accept his opinions regarding chronic inflammation and the development of ovarian cancer based upon a document which is nothing more than a current ‘draft’, devoid of specific areas of discussion highly relevant to his opinion, *e.g.*, a description of the ‘limitations’ inherent within the study and the ‘methodologies’ followed.

Furthermore, inasmuch as the Study is “ongoing”, Dr. Shih testified that his opinions regarding chronic inflammation and the development of ovarian cancer are very much subject to change.⁹² While every expert wants some flexibility to his opinion and could theoretically change his opinion if new facts come to light, Dr. Shih’s testimony that he has “no plan” as to what data to include in his “ongoing project” is simply not countenanced by the Federal Rules of Civil Procedure, which require a complete report of the proffered witness’s opinions and their basis. Dr. Shih’s interim “Study Report” offers none of that and is accordingly an unreliable basis of opinion:

- Q. A moment ago, you testified that it could change, your opinions could change. You state, again, this is ongoing projects, ongoing results.
- A. **Yes.**
- Q. The – as you sit here today, do you know if the version that you submit for peer review and publication will have co-authors with you?

⁹² *Id.* at 101:18-24.

A. **I have no plan yet what kind of other data will be included.** So I cannot answer the question for the future tense.

Q. Is it fair to say then that your study report as provided today is an unfinished product?

A. **It is an ongoing project.**⁹³

As detailed in the PSC's *Omnibus Brief*, the second part of the Third Circuit's three-prong test of admissibility of expert testimony requires an expert's testimony to be reliable.⁹⁴ Dr. Shih's opinions based upon an ongoing study with incomplete methodology (e.g., lacking several key aspects required of a peer-reviewed scientific publication including 'introduction', 'methodologies', 'result' 'limitations' and 'discussion') satisfies *none* of these considerations.

V. **CONCLUSION**

For this and the other foregoing reasons, the Court should grant the PSC's motion to exclude from this proceeding the opinions and expert reports of Drs. Shih, Neel, Boyd, and Birrer, as discussed above, including Dr. Shih's incomplete interim Study Report and his opinions based thereon.

⁹³ *Id.* at 78:9-21.

⁹⁴ *Calhoun v. Yamaha Motor Corp.*, U.S.A., 350 F.3d 316, 321 (3d Cir. 2003) ("...the testimony must be reliable...the expert's opinion must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation...") (citations omitted). *See also Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 405 (3d Cir. 2003).

Respectfully submitted,

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